

The Examiner acknowledges receipt of the lengthy information disclosure statement filed August 16, 2004. There is no requirement that applicants explain the materiality of English language references, however the cloaking of a clearly relevant reference in a long list of references may not comply with applicants' duty to disclose, see Penn Yan Boats, Inc. v. Sea Lark Boats, Inc., 359 F. Supp. 948, aff'd 479 F. 2d. 1338. There is no duty for the Examiner to consider these references to a greater extent than those ordinarily looked at during a regular search by the Examiner. Accordingly, the Examiner has considered these references in the same manner as references encountered during a normal search of Office search files.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 28-54 and 56-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dong et al.(Analytical Letters, 31(6),1998,pp.1047-1060 supplied by Applicant in the 11/3/04 IDS) in view of Walt et al. (USP 6,667,159).

Dong et al. teach measurement of antibiotic degradation under conditions of elevated temperature and alkalinity. Page 1049 teaches heating a solution of cefadroxil and sodium hydroxide in a boiling water bath for either 90 or 30 minutes. The claimed "... *at least one controlled environmental condition* ..." has been read on the taught **heating in a boiling water bath** and the claimed "... *simultaneously exposing ... to at least one controlled chemical condition* ..." has been read on the **mixing with sodium hydroxide**. Figure 3 on page 1053 shows the effects of temperature on the degradation of the drug which has been read on the claimed "... *evaluating any change of the exposed drug...*". Pages 1051 teach that copper ions increased the degradation of amoxicillin. This teaches that amoxicillin is exposed to different condition than cefadroxil which has been read on the claim 33 "... a first controlled chemical condition

and at least one other drug is exposed to a second controlled chemical condition different from the first...". Page 1049 teaches heating the amoxicillin in a boiling water bath for 20 minutes and has been read on claim 34 "... a second controlled environmental condition different from the first...". Claim 39, "component compatibility" has been read on the taught amount of degradation that occurs which reflects the compatibility with the buffers.

Dong et al. are silent to the simultaneous processing of multiple drug samples.

Walt et al. teach in column 5 lines 33-55 it is advantageous to use high throughput screening of drugs to obtain more data on more drugs in less time.

It would have been within the skill of the art to modify Dong et al. in view of Walt et al. and simultaneously test multiple drugs to gain the above advantages.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dong et al. (Analytical Letters, 31(6), 1998, pp. 1047-1060 supplied by Applicant in the 11/3/04 IDS) in view of Walt et al. (USP 6,667,159) further in view of "Pharma Safe" (cited by Applicants' in the 8/16/04 IDS).

See Dong et al. in view of Walt et al. Supra.

Dong et al. is silent to varying the humidity conditions.

"Pharma Safe" teaches that humidity is a factor in the storage of drugs and must be controlled to maintain optimal drug activity. It would have been within the skill of the art to recognize humidity could contribute to drug degradation and should be analyzed to find the optimal humidity for the storage of each drug. It would have been within the skill of the art to modify Dong et al. in view of Walt et al. further in view of "Pharma Safe"

and simultaneously test various humidity levels on the antibiotics to determine the optimal humidity for storage.

Election/Restrictions

Applicant's election of group II in the reply filed on 3/10/08 is acknowledged. Applicants do not provide any arguments traversing the restriction requirement. However, Applicant's do state claim 130 should be considered with group II because this claim is dependent upon claims in elected group II. Initially, the Office notes claim 130 cannot be examined because it is an improper multiple dependent claim. However, this is moot in light of Applicant's cancellation of claim 130 in the 3/1/04 amendments.

The requirement is still deemed proper and is therefore made FINAL.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Tuesday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1797

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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